

## § 184.1901

## 21 CFR Ch. I (4-1-04 Edition)

### § 184.1901 Triacetin.

(a) Triacetin ( $C_8H_{14}O_6$ , CAS Reg. No. 102-76-1), also known as 1,2,3,-propanetriol triacetate or glyceryl triacetate, is the triester of glycerin and acetic acid. Triacetin can be prepared by heating glycerin with acetic anhydride alone or in the presence of finely divided potassium hydrogen sulfate. It can also be prepared by the reaction of oxygen with a liquid-phase mixture of allyl acetate and acetic acid using a bromide salt as a catalyst.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 337-338, as revised by the First Supplement to the 3d Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2102 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20005.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; and humectant as defined in § 170.3(o)(16) of this chapter; and a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter, alcoholic beverages as defined in § 170.3(n)(2) of this chapter; non-alcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; chewing gum as defined in § 170.3(n)(6) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; frozen dairy dessert and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; hard candy as defined in

§ 170.3(n)(25) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989]

### § 184.1903 Tributyrin.

(a) Tributyrin ( $C_{15}H_{26}O_6$ , CAS Reg. No. 60-01-5), also known as butyrin or glyceryl tributyrate, is the triester of glycerin and butyric acid. It is prepared by esterification of glycerin with excess butyric acid.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 416, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20005.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; alcoholic beverages as defined in § 170.3(n)(2) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter; gelatins, puddings and fillings as defined in § 170.3(n)(22) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in

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this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989; 54 FR 10482, Mar. 13, 1989]

### § 184.1911 Triethyl citrate.

(a) Triethyl citrate ( $C_{12}H_{20}O_7$ , CAS Reg. No. 77-93-0) is the triethyl ester of citric acid. It is prepared by esterifying citric acid with ethyl alcohol and occurs as an odorless, practically colorless, oily liquid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 339, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent as defined in § 170.3(o)(12) of this chapter; a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and a surface-active agent as defined in § 170.3(o)(29) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63897, Dec. 12, 1994]

### § 184.1914 Trypsin.

(a) Trypsin (CAS Reg. No. 9002-07-7) is an enzyme preparation obtained from purified extracts of porcine or bovine pancreas. It is a white to tan amorphous powder. Its characterizing

enzyme activity is that of a peptide hydrolase (EC 3.4.21.4).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

### § 184.1923 Urea.

(a) Urea ( $CO(NH_2)_2$ , CAS Reg. No. 57-13-6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from  $CO_2$  by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: